



1250 Peterson Dr., Wheeling, IL 60090

Company: Viasys MedSystems
Model Tested: 60-3020
Report Number: 14483

FCC Rules and Regulations / Intentional Radiators

General Requirements

Part 15, Subpart B, Section 15.209

THE FOLLOWING **MEETS** THE ABOVE TEST SPECIFICATION

Formal Name: Viasys Navigator BioNavigation System

Kind of Equipment: Medical Location Device

Frequency Range of Operation: 62.5 kHz

Test Configuration: HandHeld Device with attached extension cable and sensor wire stylet.
(Tested with a full 9 vdc battery)

Model Number(s): 60-3020

Model(s) Tested: 60-3020

Serial Number(s): NV15-001, NV15-002

Date of Tests: August 9 & 17, 2007

Test Conducted For: Viasys MedSystems
100 Chaddick Drive
Wheeling, Illinois 60090

NOTICE: "This report must not be used by the client to claim product endorsement by NVLAP or any agency of the U.S. Government". Please see the "Additional Description of Equipment Under Test" page listed inside of this report.

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SIGNATURE PAGE

Report By:

Arnom C. Rowe
Test Engineer
EMC-001375-NE

Reviewed By:

William Stumpf
OATS Manager

Approved By:

Brian Mattson
General Manager



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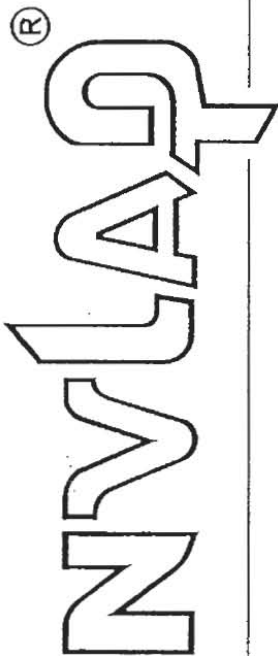


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United States Department of Commerce
National Institute of Standards and Technology



Certificate of Accreditation to ISO/IEC 17025:2005

NVLAP LAB CODE: 100276-0

D.L.S. Electronic Systems, Inc.
Wheeling, IL

is accredited by the National Voluntary Laboratory Accreditation Program for specific services,
listed on the Scope of Accreditation, for:

ELECTROMAGNETIC COMPATIBILITY AND TELECOMMUNICATIONS

This laboratory is accredited in accordance with the recognized International Standard ISO/IEC 17025:2005.
This accreditation demonstrates technical competence for a defined scope and the operation of a laboratory quality management system (refer to joint ISO-ILAC-IAF Communique dated 18 June 2005).



2007-10-01 through 2008-09-30

Effective dates

Dolly A. Bures
For the National Institute of Standards and Technology

NVI AP-01C (REV. 2006-09-13)



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1.0 SUMMARY OF TEST REPORT

It was found that the Viasys Navigator BioNavigation System, Model Number(s) 60-3020, **meets** the radio interference radiated emission requirements of the FCC "Rules and Regulations", Part 15, Subpart C, 15.209, general requirements for Intentional Radiators. The AC Power Line conducted emissions test was not required because the Viasys Navigator BioNavigation System is powered from a D.C. power source. It does not have a line cord to plug into the A.C. power line.

2.0 INTRODUCTION

On August 9 & 17, 2007, a series of radio frequency interference measurements was performed on Viasys Navigator BioNavigation System, Model Number(s) 60-3020, Serial Number: NV15-001, NV15-002. The tests were performed according to the procedures of the FCC as stated in the "Methods of Measurement of Radio-Noise Emissions for Low-Voltage Electrical and Electronic Equipment in the Range of 9 kHz to 40 GHz" found in the American National Standards Institute, ANSI C63.4-2003 and applicable FCC Part 15 Rules and procedures. Tests were performed by personnel of D.L.S. Electronic Systems, Inc. who are responsible to Donald L. Sweeney, Senior EMC Engineer.

D.L.S. Electronic Systems, Inc. is a full service EMC/Safety Testing Laboratory accredited to ISO 17025. NVLAP Certificate and Scope can be viewed at <http://www.dlsemc.com/certificate>. Our facilities are registered with the FCC, Industry Canada, and VCCI.

Main Test Facility:

D.L.S. Electronic Systems, Inc.
1250 Peterson Drive
Wheeling, Illinois 60090

O.A.T.S. Test Facility:

D.L.S. Electronic Systems, Inc.
166 S. Carter Street
Genoa City, Wisconsin 53128

3.0 OBJECT

The purpose of this series of tests was to determine if the test sample could meet the radio frequency interference emission requirements of the FCC "Rules and Regulations", Part 15, Subpart C, Sections 15.33, 15.207, 15.209 for Intentional Radiators (general requirements) that operate in the frequency range 9 kHz to 960 MHz and above.



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4.0 TEST SET-UP

All emission tests were performed at D.L.S. Electronic Systems, Inc. and set up according to the ANSI C63.4-2003, Annex H. All radiated emissions tests were performed with the test item placed on a 80 cm high rotating non-conductive table, located in the test room. Equipment normally operated on the floor was placed on a metal covered turntable which is flush with the surrounding conducting ground plane. The ground plane has an electrical isolation layer over its surface approximately 7 mm thick. The EUT is separated from the turntable ground plane by a non-conductive layer. The equipment under test was set up according to ANSI C63.4-2003, Sections 6 and 8.

NOTE:

During testing the Viasys Navigator BioNavigation System was tested in the “Continuous Transmit Mode”.

5.0 TEST EQUIPMENT (Bandwidths and Detector Function)

All preliminary data below 1000 MHz was automatically plotted using the ESI 26/40 Fixed Tuned Receiver. The data was taken using Peak, Quasi-Peak or the Average Detector Functions as required. This information was then used to determine the frequencies of maximum emissions. Above 1000 MHz, final data was taken using the Average Detector.

Below 1000 MHz, final data was taken using the ESI 26/40 Fixed Tuned Receiver. These plots were made using the Peak or Quasi-Peak Detector functions, with manual measurements performed on the EUT emissions using the Quasi-Peak or the Average Detector Function of the ESI 26/40 Fixed Tuned Receiver as required. The bandwidths shown below are specified by ANSI C63.4-2003, Section 4.2.

Frequency Range	Bandwidth (-6 dB)
10 to 150 kHz	200 Hz
150 kHz to 30 MHz	9 kHz
30 MHz to 1 GHz	120 kHz

A list of the equipment used can be found in Table 1. All primary equipment was calibrated against known reference standards with a verified traceable path to NIST.



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6.0 AMBIENT MEASUREMENTS

For emissions measurements, broadband antennas and an EMI Test Receiver with a panoramic spectrum display are used. First the frequency range is scanned and displayed on the test receiver display. Next the scanned frequency range is divided into smaller ranges, and then it is manually tuned through to determine the emissions from the EUT. A headset or loudspeaker is connected to the test receiver's AM/FM demodulated output as an aid in detecting ambient signals and finding frequencies of significant emission from the EUT. If there is any doubt as to the source of the emission, it is further investigated by rotating the EUT, or by disconnecting the power from the EUT.

The EUT is set up in its typical configuration and operated in its various modes. For tabletop systems, cables are manipulated within the range of likely configurations. For floor-standing equipment, the cables are located in the same manner as the user would install them and no further manipulation is made. If the manner of cable installation is not known, or if it changes with each installation, cables or wires for floor-standing equipment shall be manipulated to the extent possible to produce the maximum level of emissions. For each mode of operation, the frequency spectrum is monitored. Variations in antenna height, antenna polarization, EUT azimuth, and cable or wire placement (each variable within bounds specified elsewhere) are explored to produce the emissions that have the highest amplitude relative to the limit. These methods are performed to the specifications in ANSI C63.4-2003.



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7.0 DESCRIPTION OF TEST SAMPLE: (See also Paragraph 8.0)

7.1 Description:

The NAVIGATØR® BioNavigation System is designed to aid in the placement of central venous catheters (CVCs) by indicating the position of the catheter tip inside the body during the catheter insertion procedure.

The NAVIGATØR BioNavigation System consists of:

1. NAVIGATØR Instrument - a hand-held, battery powered, electronic locating instrument.
2. MAPCath® - a sterile, disposable, closed-end plastic stylet with a miniature, magnetically activated positioning (MAP) sensor in its tip. The MAPCath is supplied assembled with a Tuohy-Borst Adaptor in a sterile pouch.
3. Extension Cable - an electrical cable to connect the NAVIGATØR Instrument to the banded end of the MAPCath stylet.

The NAVIGATØR Instrument emits a low level, high frequency electromagnetic field that is detected by the sensor in the tip of the MAPCath stylet. The position of the MAPCath stylet tip inside the patient is indicated externally by the position shown on the NAVIGATØR display. Audible and visual indicators signal the operator when the NAVIGATØR is positioned directly over the sensor in the MAPCath stylet tip. The navigator utilizes integrated V-coil & H-coil antennas.

7.2 PHYSICAL DIMENSIONS OF EQUIPMENT UNDER TEST

Length: 8.5" Width: 2" Height: 4"

7.3 LINE FILTER USED:

9 Vdc Battery Powered Device

7.4 INTERNAL CLOCK FREQUENCIES:

Switching Power Supply Frequencies:

900 kHz

Clock Frequencies:

8.0 MHz



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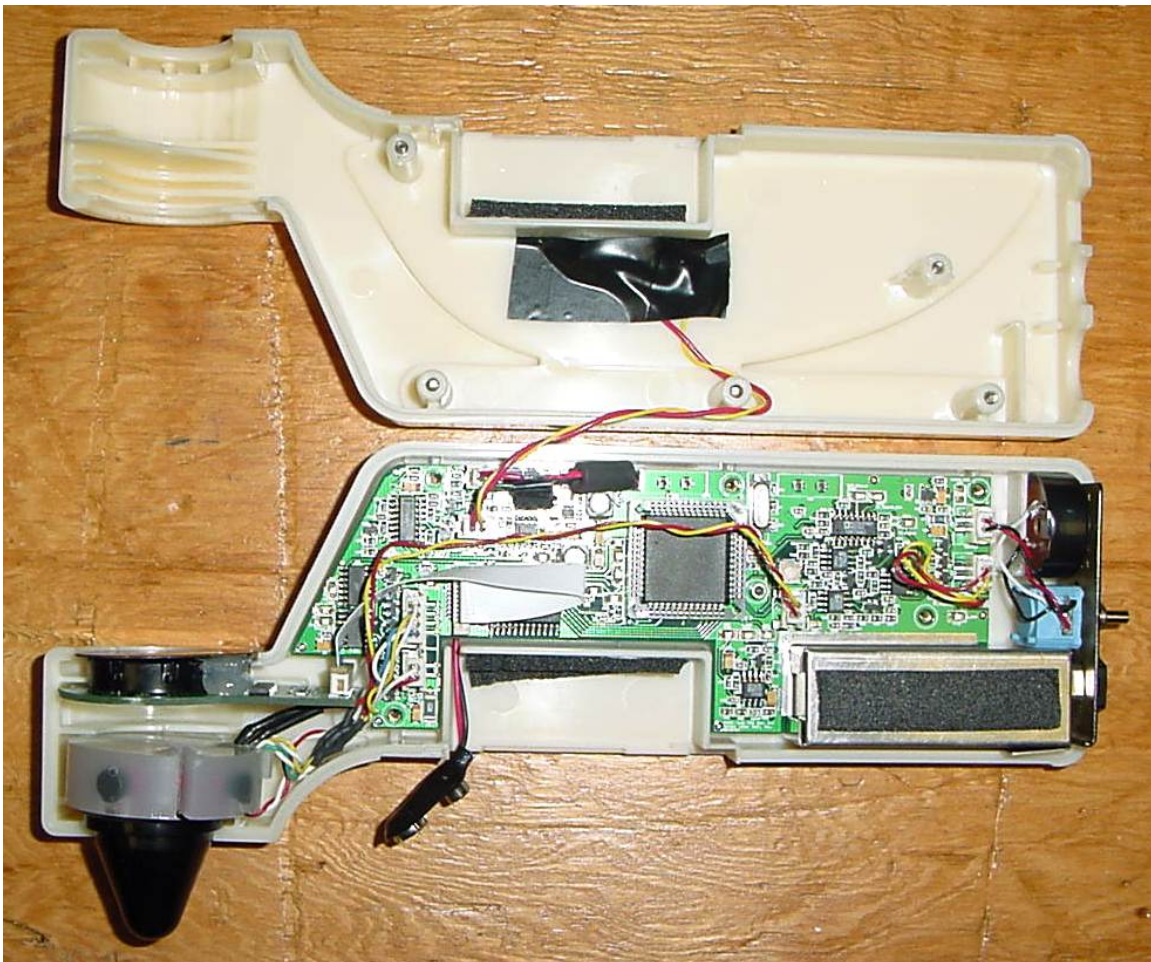
7.0 DESCRIPTION OF TEST SAMPLE: (CONT)

7.5 DESCRIPTION OF ALL CIRCUIT BOARDS:

- | | |
|-------------------------|-----------------------|
| 1. PCB, Main Nav 1.5 | PN: 3600 HLB Rev. 2-1 |
| 2. PCB, Display Nav 1.5 | PN: 3601 HLB Rev. 2-1 |

8.0 ADDITIONAL DESCRIPTION OF TEST SAMPLE: (See also Paragraph 7.0)

- 1: Added Fair-Rite #2643250402 (with one pass) to Battery wires inside the EUT at circuit board end. (See the following photo for location of ferrite core).





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9.0 PHOTO INFORMATION AND TEST SET-UP

Item 0 Viasys Navigator BioNavigation System

Model Number: 60-3020 Serial Number: NV15-001, NV15-002

Item 1 Non-shielded extension cable and Sensor Wire with Plastic Shells. 2m



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10.0 RADIATED PHOTOS TAKEN DURING TESTING



WORST CASE ORTHOGONAL AXIS



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11.0 RESULTS OF TESTS

The radio interference emission charts can be seen on the pages at the end of this report. Data sheets indicating the test measurements taken during testing can also be found at the end of this report.

12.0 CONCLUSION

It was found that the Viasys Navigator BioNavigation System, Model Number(s) 60-3020 **meets** the radio interference radiated emission requirements of the FCC "Rules and Regulations", Part 15, Subpart C, Sections 15.209, general requirements for Intentional Radiators. The conducted emissions test was not required because the Viasys Navigator BioNavigation System is powered from a D.C. power source. It does not have a line cord to plug into the A.C. power line.



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TABLE 1 – EQUIPMENT LIST

Test Equipment	Manufacturer	Model Number	Serial Number	Frequency Range	Cal Due Dates
Receiver, RF, Tuned	Rohde & Schwarz	ESI 40	837808/005	20 Hz – 40 GHz	12/2007
Preamp, RF	Rohde & Schwarz	TS-PR10	032001/005	26 GHz-40 GHz	1/2008
Biconical Antenna	EMCO	3104C	9701-4785	20-220MHz	2/2008
Log Periodic Antenna	EMCO	3146	9702-4895	200MHz-1GHz	3/2008
Active Loop Antenna	EMCO	6502	9307-2839	9kHz-30MHz	8/2008

All primary equipment is calibrated against known reference standards with a verified traceable path to NIST.



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APPENDIX A

RADIATED DATA

AND

CHARTS TAKEN DURING TESTING

9 kHz – 30 MHz

FCC Part 15.209

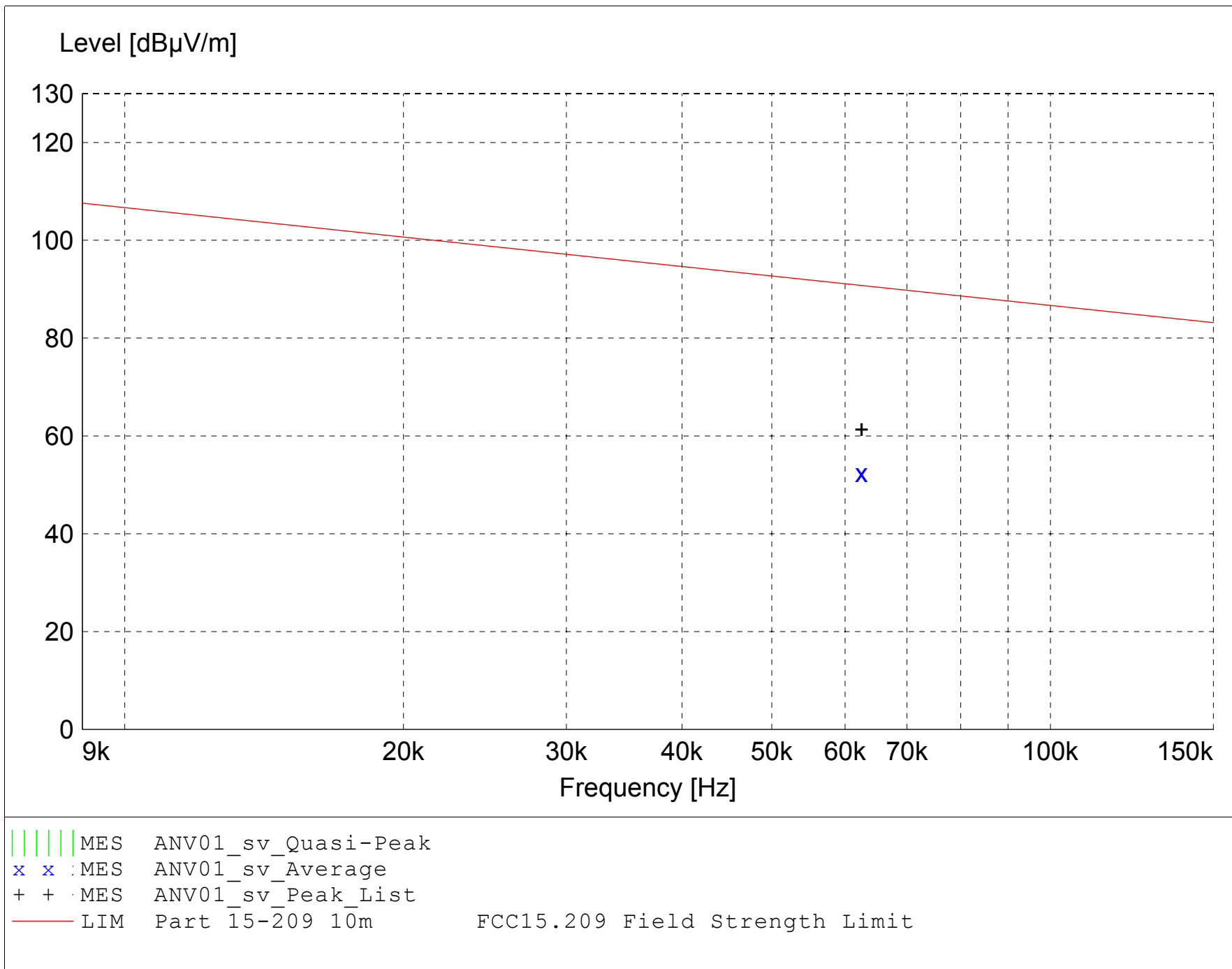
Electric Field Strength

EUT: Viasys Navigator BioNavigation System Model: 60-3020
Manufacturer: Viasys MedSystems 1
Operating Condition: 73 deg. F; 71% R.H.
Test Site: DLS O.F. Site 3
Operator: Craig B
Test Specification:
Comment: Transmit at 62.5 kHz
Date: 08-09-2007

TEXT: "Site 3 LowH 10M Act"

Short Description: Test Set-up 9kHz to 30MHz H
TEST EQUIPMENT: Receiver --- Rohde&Schwarz ESI40 SN: 837808/005
Antennas --- EMCO Active Loop Model: 6502 SN: 1027

TEST SET-UP: EuT Measured at 10 Meters with H-FIELD Antenna



MEASUREMENT RESULT: "ANV01_sv_Final"

8/16/2007 1:45PM

Frequency	Level	Antenna Factor	System Loss	Total Level	Limit	Margin	Height Ant.	EuT Angle	Final Detector	Comment
MHz	dBμV	dBμV/m	dB	dBμV/m	dBμV/m	dB	m	deg		
0.062500	41.01	11.25	0.1	52.3	90.8	38.4	1.00	0	AVERAGE	Fundamental

FCC Part 15.209

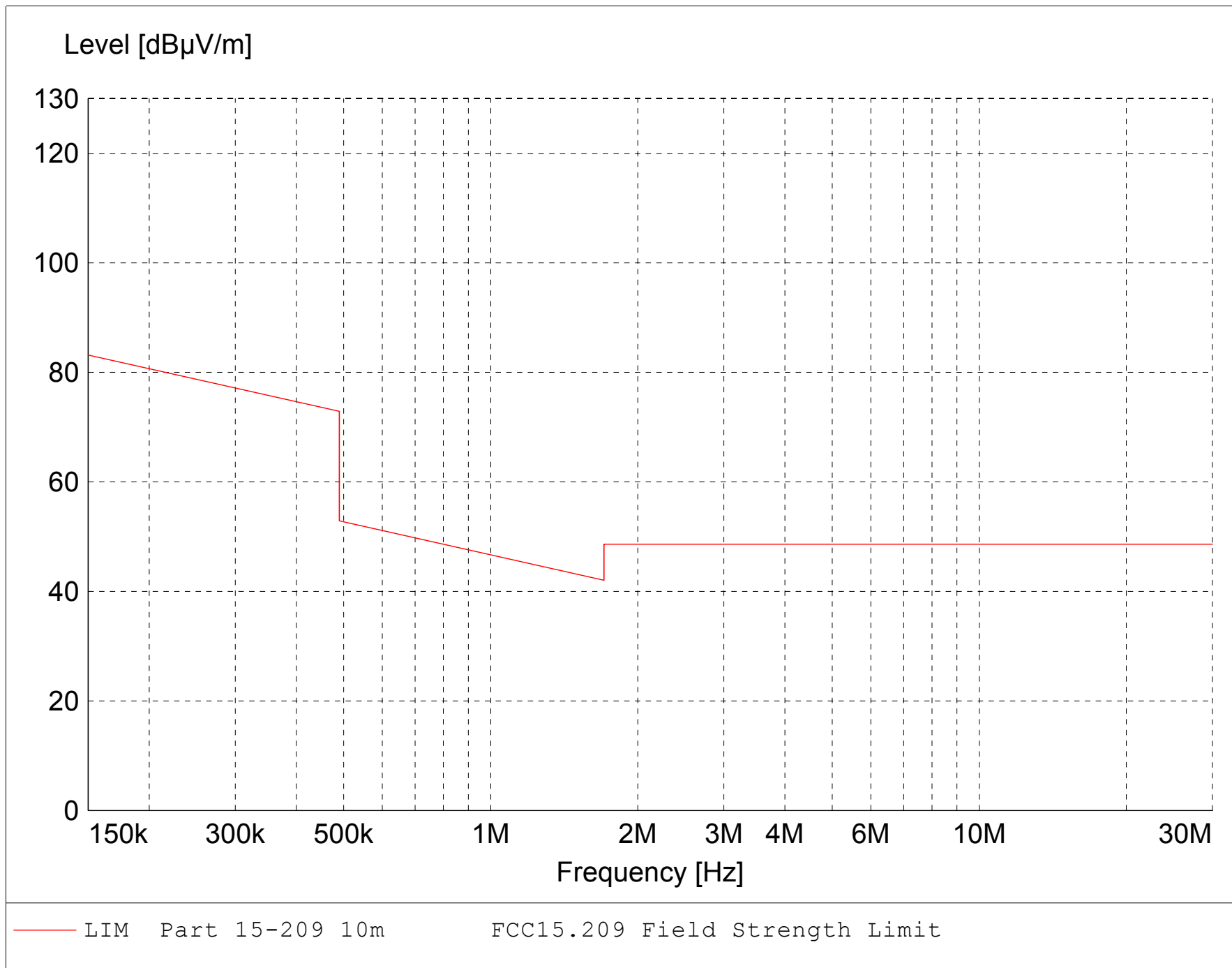
Electric Field Strength

EUT: Viasys Navigator BioNavigation System Model: 60-3020
Manufacturer: Viasys MedSystems 1
Operating Condition: 73 deg. F; 71% R.H.
Test Site: DLS O.F. Site 3
Operator: Craig B
Test Specification:
Comment: Transmit at 62.5 kHz
Date: 08-09-2007

TEXT: "Site 3 LowH 10M Act"

Short Description: Test Set-up 9kHz to 30MHz H
TEST EQUIPMENT: Receiver --- Rohde&Schwarz ESI40 SN: 837808/005
Antennas --- EMCO Active Loop Model: 6502 SN: 1027

TEST SET-UP: EuT Measured at 10 Meters with H-FIELD Antenna





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APPENDIX B

RADIATED DATA

AND

CHARTS TAKEN DURING TESTING

30 MHz – 1000 MHz

FCC Part 15 Class B

Electric Field Strength

EUT: Viasys Medsystems 60-3020 transmitter
Manufacturer: Viasys MedSystems 1
Operating Condition: 73 deg. F; 71% R.H.
Test Site: DLS O.F. Site 3
Operator: Craig B
Test Specification:
Comment: Transmit at 62.5 kHz
Date: 08-09-2007

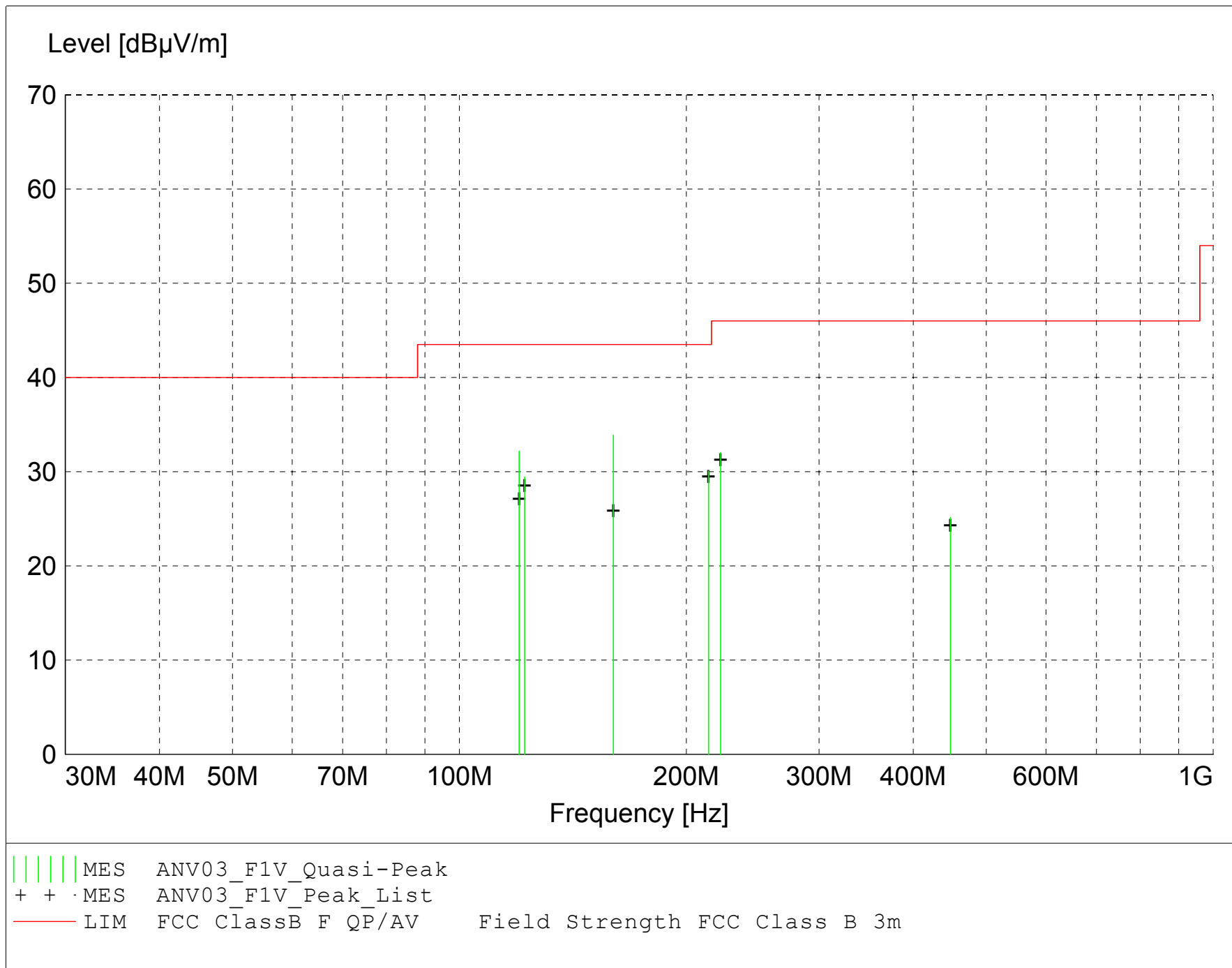
TEXT: "Site 3 MidV 3M"

Short Description: Test Set-up Vert30-1000MHz
TEST EQUIPMENT: Receiver --- Rohde&Schwarz ESI 40 SN: 837808/005

Antennas ---
Biconical -- EMCO 3104C SN: 9701-4785
Log Periodic -- EMCO 3146 SN: 9702-4895

Pre-Amp --- Rohde&Schwarz TS-PR10 SN: 032001/005

TEST SET-UP: EUT Measured at 3 Meters with VERTICAL Antenna Polarization



MEASUREMENT RESULT: "ANV03_F1V_Final"

8/9/2007 1:14PM

Frequency	Level	Antenna	System	Total	Limit	Margin	Height	EuT	Final	Comment
MHz	dBμV	Factor	Loss	Level			Ant.	Angle	Detector	
		dBμV/m	dB	dBμV/m	dBμV/m	dB	m	deg		
160.035000	43.80	13.43	-23.3	33.9	43.5	9.6	1.00	90	QUASI-PEAK	None
120.025000	43.30	12.31	-23.4	32.2	43.5	11.3	1.00	180	QUASI-PEAK	None
214.050000	42.15	10.36	-22.4	30.1	43.5	13.4	1.00	315	QUASI-PEAK	None
222.050000	43.97	10.46	-22.4	32.0	46.0	14.0	1.00	315	QUASI-PEAK	None
122.025000	40.36	12.54	-23.4	29.5	43.5	14.0	1.00	180	QUASI-PEAK	None
448.100000	29.96	16.19	-21.0	25.1	46.0	20.9	1.00	60	QUASI-PEAK	None

FCC Part 15 Class B

Electric Field Strength

EUT: Viasys Medsystems 60-3020 transmitter
Manufacturer: Viasys MedSystems 1
Operating Condition: 73 deg. F; 71% R.H.
Test Site: DLS O.F. Site 3
Operator: Craig B
Test Specification:
Comment: Transmit at 62.5 kHz
Date: 08-09-2007

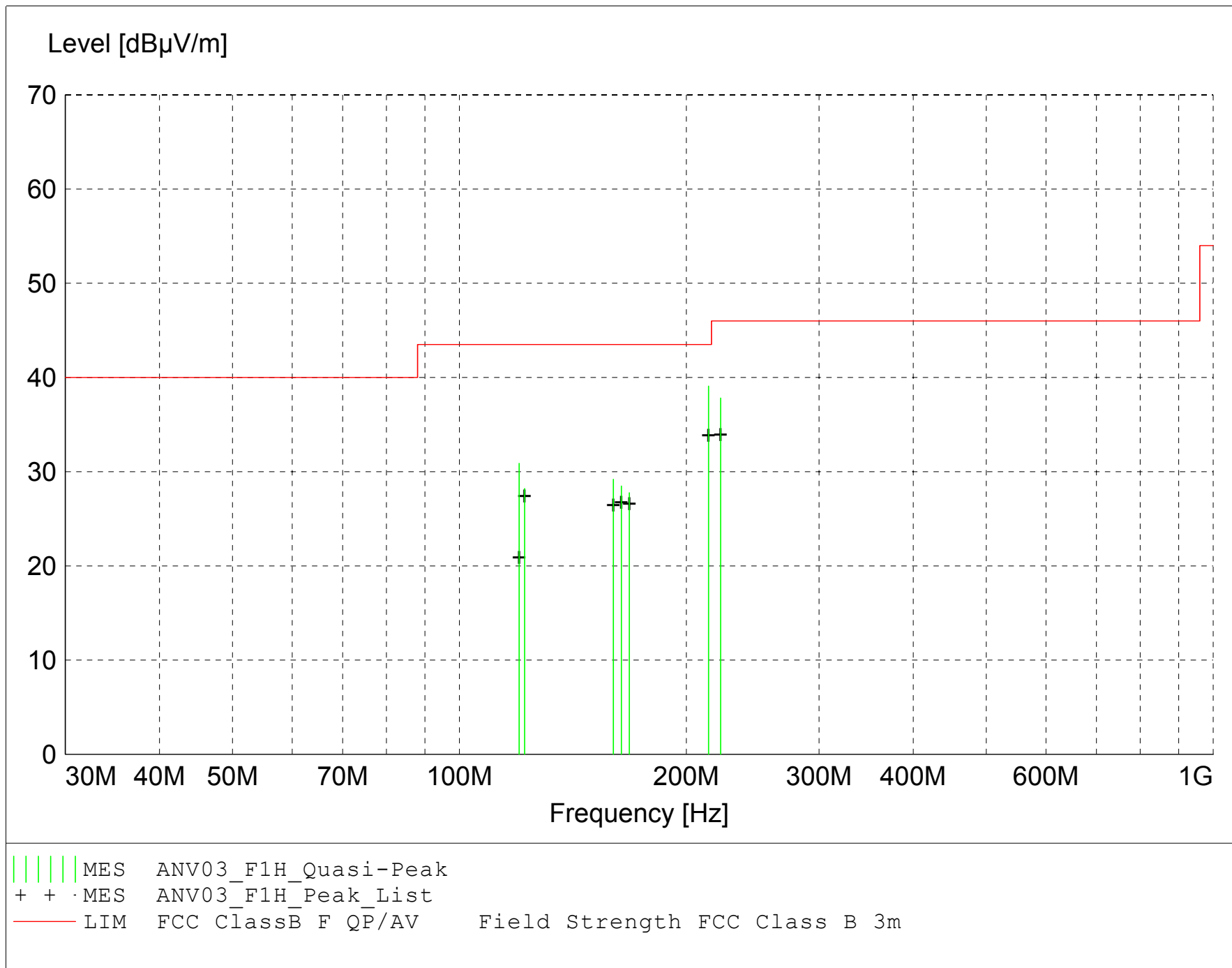
TEXT: "Site 3 MidH 3M"

Short Description: Test Set-up Horz30-1000MHz
TEST EQUIPMENT: Receiver --- Rohde&Schwarz ESI 40 SN: 837808/005

Antennas ---
Biconical -- EMCO 3104C SN: 9701-4785
Log Periodic -- EMCO 3146 SN: 9702-4895

Pre-Amp --- Rohde&Schwarz TS-PR10 SN: 032001/005

TEST SET-UP: EUT Measured at 3 Meters with HORIZONTAL Antenna Polarization



MEASUREMENT RESULT: "ANV03_F1H_Final"

8/9/2007 1:07PM

Frequency	Level	Antenna	System	Total	Limit	Margin	Height	EuT	Final	Comment
MHz	dBμV	Factor	Loss	Level			Ant.	Angle	Detector	
		dBμV/m	dB	dBμV/m	dBμV/m	dB	m	deg		
214.050000	51.18	10.36	-22.4	39.1	43.5	4.4	1.60	100	QUASI-PEAK	None
222.050000	49.76	10.46	-22.4	37.8	46.0	8.2	1.10	100	QUASI-PEAK	None
120.030000	42.02	12.31	-23.4	30.9	43.5	12.6	1.70	280	QUASI-PEAK	None
160.030000	39.10	13.43	-23.3	29.2	43.5	14.3	1.10	315	QUASI-PEAK	None
164.035000	37.76	13.95	-23.2	28.5	43.5	15.0	1.00	290	QUASI-PEAK	None
122.025000	39.11	12.54	-23.4	28.2	43.5	15.3	2.60	290	QUASI-PEAK	None
168.035000	36.85	14.03	-23.1	27.8	43.5	15.7	1.00	290	QUASI-PEAK	None



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APPENDIX C

DUTY CYCLE GRAPHS

PART 15.209



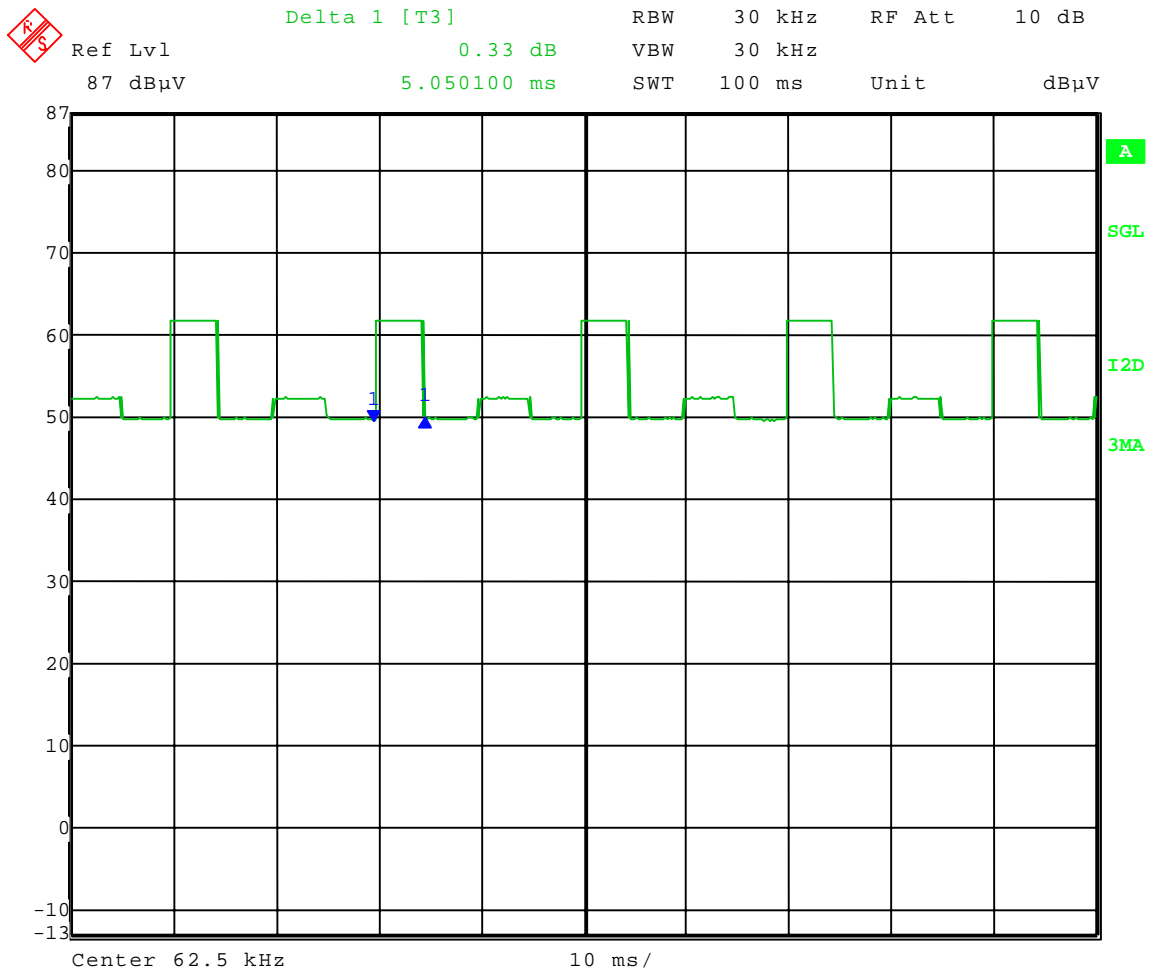
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Test Date: 08-17-2007
Company: Viasys MedSystems
EUT: Viasys Navigator BioNavigation System Model: 60-3020
Test: Duty Cycle
Operator: Craig B

Comment: One pulse = 5.05 ms
Total ON time during 100 ms = 5.05 ms X 10 = 50.5 ms

Duty Cycle = 50.5%



Date: 17.AUG.2007 10:41:14



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APPENDIX D

20 dB BANDWIDTH GRAPHS

PART 15.209

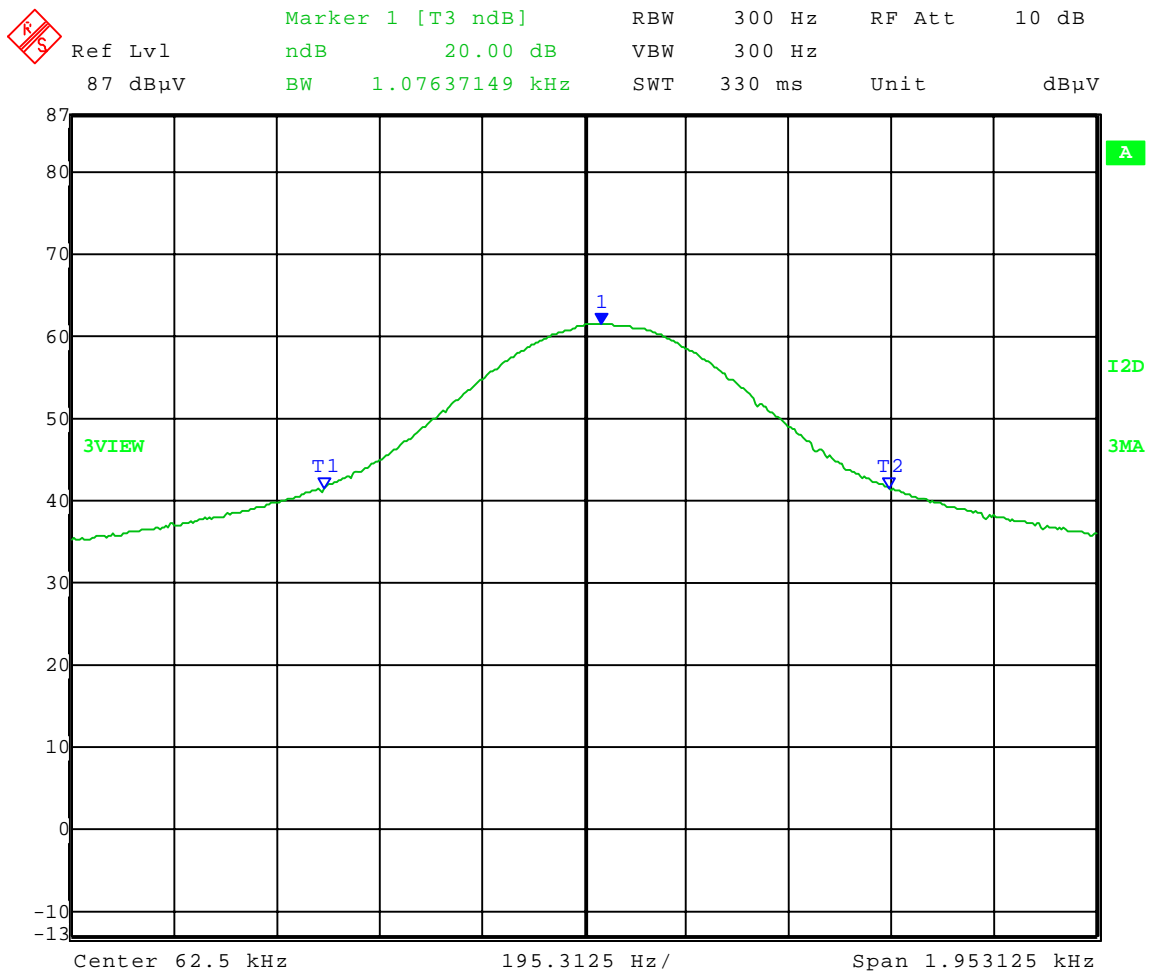


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Test Date: 08-17-2007
Company: Viasys MedSystems
EUT: Viasys Navigator BioNavigation System Model: 60-3020
Test: 20 dB Bandwidth - Radiated
Operator: Craig B
Comment: Frequency: 62.5 kHz

20 dB Bandwidth = 1.08 kHz



Date: 17.AUG.2007 10:33:52